EUROPEAN
COMMISSION

Bruxelles, 3.8.2017
C(2017) 5606 (final)

COMMISSION IMPLEMENTING DECISION

of 3.8.2017

amending the marketing authorisation granted by Decision C(2004)3653 for "Apidra - Insulin glulisine", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Sanofi-Aventis Deutschland GmbH in accordance with Regulation (EC) No 1234/2008 and in accordance with Article 61(3) of Directive 2001/83/EC,

Having regard to the opinion of the European Medicines Agency, formulated on 15 September 2016 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The European Medicines Agency's opinion is favourable to the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(2) Decision C(2004)3653 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(3) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)3653 should therefore be replaced.

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 334, 12.12.2008, p. 7.
3 OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, 3.8.2017

For the Commission

Xavier PRATS MONNÉ
Director-General